SUPPORT FOR THE AMENDMENTS

The present amendment cancels claim 6, and amends claims 1 and 8. Support for the amendment to claims 1 and 8 is found at specification page 9, lines 17-21. It is believed that these amendments have not resulted in the introduction of new matter.

REMARKS

Claims 1-5 and 7-19 are currently pending in the present application. Claim 6 has been cancelled, and claims 1 and 8 have been amended, by the present amendment. Claims 14 and 15 stand withdrawn from consideration by the Examiner as being directed to a non-elected invention.

Applicants wish to extend their appreciation to Examiner Milligan for the helpful and courteous discussion held on February 24, 2010, with their undersigned Representative. During the meeting, the prior art rejections were discussed, along with potential claim amendments, arguments and/or evidence for overcoming the rejections. The content of this discussion is believed to be reflected in the remarks set forth herein.

The rejections of: (1) claims 1, 4-7, 10 and 16-19 as being anticipated over Hoshino (JP 2002-560764); (2) claims 1-12 and 16-19 as being obvious over Koike (U.S. 2004/0033258, which is the English language equivalent of WO 02/3040); and (3) claim 13 as being obvious over Koike in view of Ishikawa (Chem. Pharm. Bull), are obviated by amendment, with respect to claims 1-5 and 7-19, which incorporates into amended claim 1 the limitation that the weight ratio of mannitol to other saccharide(s) is (98-75) : (2-25).

Amended claim 1 is directed to a composition for rapid disintegrating tablets in an oral cavity, wherein the composition comprises: (a) 40-90 parts by weight of saccharides comprised of a combination of mannitol and one or more of other saccharide(s) selected from sorbitol, erythritol, maltitol, lactose, sucrose, glucose, fructose, maltose, trehalose, paratinit and paratinose; (b) 1-30 parts by weight of an inorganic excipient; and (c) 5-40 parts by weight a disintegrating agent, wherein a total amount of components (a), (b) and (c) is 100 parts by weight, and wherein a weight ratio of mannitol to other saccharide(s) is (98-75) : (2-25).

Hoshino describes a rapid disintegration tablet composition comprising: 200 parts by wt. of D-mannitol; 350 parts by wt. of erythritol; 50 parts by wt. of calcium silicate; 50 parts by wt. of hydroxypropyl cellulose; and 300 parts by wt. of acetaminophen (See e.g., abstract, Example 1).

Koike describes a quick disintegration tablet composition comprising: 147 g of mannitol (59 wt. %); 72.4 g of lactose (29 wt. %); 1.5 g of magnesium stearate (0.6 wt. %); 18.0 g of low-substituted hydroxypropyl cellulose (7.2 wt. %); and 10.3 g of crystalline cellulose (4.1 wt. %), wherein mannitol and lactose are present in a weight ratio of (67) : (33) (See e.g., Example 6, [0262]-[0265]).

Ishikawa describes a rapid disintegration tablet composition comprising microcrystalline cellulose having a mean particle diameter of 7-32 μm (See e.g., abstract).

Hoshino describes a weight ratio of D-mannitol to erythritol of (36) : (64), which is clearly outside the claimed weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25).

Koike describes a weight ratio of mannitol to lactose of (67) : (33), which is clearly outside the claimed weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25).

Ishikawa fails to compensate for the above-identified deficiencies of Hoshino and Koike.

Applicants respectfully submit that a skilled artisan would not have arrived at the claimed weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25), based on the disclosures of Hoshino, Koike and/or Ishikawa, absent impermissible hindsight reconstruction, thereby precluding a *prima facie* case of unpatentability.

Since Hoshino, Koike and Ishikawa, when considered alone or in combination, fail to disclose or suggest a weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25), as presently claimed, these references necessarily fail to anticipate or render obvious to a skilled artisan the composition of the present invention.

Assuming *arguendo* that sufficient motivation and guidance is considered to have been provided by the cited references to arrive at the claimed weight ratio of mannitol to other saccharide(s) of (98-75) : (2-25), which is clearly not the case, such a case of obviousness is rebutted by a showing of superior properties.

As discussed in the present specification and shown by the comparative experimental data presented in the present specification and Table A of the 37 C.F.R. § 1.132 Declaration appended herewith, which is reproduced hereinbelow for the Examiner's convenience, Applicants have discovered that the tablet compositions of Examples B, 9 and C, which comprise mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties, as compared to the inferior properties exhibited by the tablet compositions of Comparative Examples A and D, which comprise mannitol and other saccharide(s) outside the claimed weight ratio of (98-75) : (2-25) (See e.g., page 3, lines 20-25, page 4, lines 1-6, page 6, lines 4-9, page 9, lines 17-21, page 10, lines 3-6, page 30, Example 9).

Table A

Tablet Composition	Comparative Example A	Example B	Example 9	Example C	Comparative Example D
Weight Ratio of mannitol : lactose	100 : 0	98 : 2	90 : 10	75 : 25	65 : 35
Mannitol	280	274.4	252	210	182
Lactose	0	5.6	28	70	98
Crystalline cellulose	60	60	60	60	60
Crospovidone	32	32	32	32	32
Mg aluminometasillicate	28	28	28	28	28
Tabletting Pressure (kgf)	340	380	310	260	240
Oral Disintegration Time (sec)	16	26	17	34	**73**
Tabletting troubles	**Yes***	No	No	No	No

* The tablet composition stuck to the punches, and the shape of the obtained tablets was not satisfactory.

It should be mentioned that the tablet compositions of Examples B and C, and Comparative Examples A and D, were prepared according Example 9 in the present specification, with the exception of alternatively comprising mannitol and the other saccharide(s) in the weight ratio specified in Table A above.

This evidence clearly demonstrates that the tablet compositions of Examples B, 9 and C, which comprise mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention, exhibit superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties, as compared to the inferior tabletting property exhibited by the tablet composition of Comparative Example A, which has a weight ratio of mannitol and other saccharide(s) of (100) : (0), and the inferior oral disintegration time property exhibited by the tablet composition of Comparative Example D, which has a weight ratio of mannitol and other saccharide(s) of (65) : (3), which is similar to the weight ratio described in Koike.

The cited references when considered alone or in combination, fail to disclose or suggest a composition comprising mannitol and other saccharide(s) in a weight ratio of (98-75) : (2-25), as presently claimed. Accordingly, the cited references necessarily fail to recognize that superior properties with respect to an excellent balance of both improved oral disintegration times and tabletting properties are exhibited when a composition comprises mannitol and other saccharide(s) in the claimed weight ratio of (98-75) : (2-25) in accordance with an exemplary aspect of the present invention.

Withdrawal of these grounds of rejection is respectfully requested.

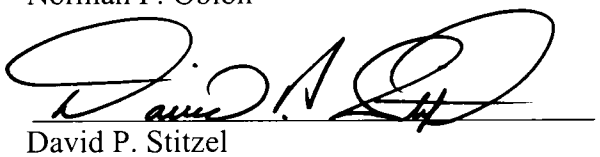
Applicants respectfully request that the provisional obviousness-type double patenting rejections of claims 1-13 and 16-19 over claims 1, 3-28 and 30-32 of copending application 10/945,049 (Tanaka '240, U.S. 2005/0106240, be held in abeyance until allowable subject matter in the present application is indicated.

The rejection of claim 6 under 35 U.S.C. § 112, second paragraph, is obviated by amendment with respect to the cancellation of said claim. Withdrawal of this ground of rejection is respectfully requested.

In conclusion, Applicants submit that the present application is now in condition for allowance and notification to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



David P. Stitzel
Attorney of Record
Registration No. 44,360

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 06/04)